



THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Kevin H. Gillespie
Serial No. : 09/458,415
Filed : December 10, 1999
Title : SHOE OUTSOLE

Art Unit : 3728
Examiner : A. Stashick

Commissioner for Patents
Washington, D.C. 20231

DECLARATION OF DR. EDWARD MOSTONE

I, Dr. Edward Mostone, declare as follows:

1. I am a podiatrist. A copy of my curriculum vitae is attached.
2. There are significant differences between infant feet and adult feet. Infant feet are not simply smaller versions of adult feet. For instance, an infant's foot is hyper-mobile, and has little or no arch, due to "baby fat." Moreover, the bones of an infant are very soft. Some bones do not even appear on an x-ray of an infant's foot, because ossification has not yet occurred. As a result, the bone structure of an infant's foot is moldable until the child is at least 4 to 6 years old. These characteristics do not occur in most normal adult feet.
3. The gait of an infant is also different from that of an adult. Infants tend to waddle, with their toes directed outward in a "duck walk." A normal, adult gait is generally not achieved until the child is 6 to 8 years old. Infants also have great difficulty balancing on two feet -- as a result many infants tend to walk with their arms raised, in an effort to balance. Improper footwear can exacerbate these problems. Most normal adults do not suffer from these problems.

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

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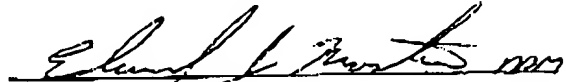
EDWARD J MOSTONE
Typed or Printed Name of Person Signing Certificate

Applicant : Kevin H. Gillespie
Serial No. : 09/458,415
Filed : December 10, 1999
Page : 2

Attorney's Docket No.: 06129-156001

4. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Date: 12-4-01


Dr. Edward Mostone

20152437.1

Curriculum Vitae

NAME: Edward J. Mostone, D.P.M.
ADDRESS: 678 Massachusetts Avenue, Cambridge, MA 02139
PLACE OF BIRTH: Boston, MA

May 3, 2001

EDUCATION:

1985	Doctor of Podiatric Medicine	New York College of Podiatric Medicine, New York, NY
1981	Bachelor of Arts	Assumption College, Worcester, MA

POSTDOCTORAL TRAINING:

1986-1987	Chief Resident in Podiatric Medicine and Surgery	Baptist Medical Center, Brooklyn, NY
1985-1986	Resident in Podiatric Medicine and Surgery	Baptist Medical Center, New York, NY

LICENSURE AND CERTIFICATION:

1986	Podiatry License	Massachusetts
1986	Podiatry License	Connecticut
1985	Podiatry License	New York
1991	American Board of Podiatric Orthopaedics - Board Certified	
1992	American Board of Podiatric Surgery - Board Certified	
1998	American Academy of Pain Management	

PROFESSIONAL APPOINTMENTS:

Academic Appointments:

1997 Clinical Instructor in Orthopaedics, Tufts University School of Medicine

Hospital Appointments:

1987	Staff Member,	The Cambridge Hospital
1987	Staff Member,	Lawrence Memorial Hospital
1988	Staff Member,	Mount Auburn Hospital
1989	Associate Staff,	St. Vincent's Hospital
1993	Courtesy Staff,	Winchester Hospital
1996	Associate Staff	New England Medical Center
1996	Staff Member,	Marguerite D'Youville Hospital

Other Professional Positions, Major Visiting Appointments, Relevant Community Service:

1985	Clinical Instructor, Medical Mission, San Paolo, Brazil
1985-1987	Associate Director of Podiatric Services, New York State Police
1987-1990	Podiatrist, Park Street Homeless Shelter, Boston, MA
1988-1990	Team Podiatrist, Boston Public School System

Edward J. Mostone, D.P.M.

Curriculum Vitae

Page 2 of 7

May 3, 2001

- 1996 Visiting Physician, Medical Mission, Baltic American Clinic, Vilnius Emergency Hospital, Vilnius, Lithuania
- 1996 Visiting Lecturer, Staten Island University Hospital
- 1997 Weekly Instructor in Podiatry, Marguerite D'Youville Hospital School of Nursing
- 1999 Visiting Lecturer, Staten Island University Hospital

AWARDS AND HONORS:

- 1987 Baptist Medical Center, Scientific Publication Award, Keller-Austin Unionectomy.
- 1987 Dr. Frank Esposito Award, Excellence in Residents' Training
- 1996 Baltic American Clinic, Vilnius, Lithuania, Certificate of Appreciation
- 1994 Clinical Teacher of the Year, Podiatry Residency Program, The Cambridge Hospital

PRINCIPAL CLINICAL AND HOSPITAL SERVICES RESPONSIBILITIES:

- 1991-1998 Chief, Division of Podiatric Medicine, The Cambridge Hospital
- 1989-1998 Associate Director, Podiatric Surgical Residency Program, The Cambridge Hospital
- 1992-1996 Chairman, Podiatry Residence Selection Committee
- 1990-1992 Chief, Division of Podiatric Medicine, The Heritage Hospital
- 1996-present Director, Division of Podiatric Medicine, Marguerite D'Youville Hospital

MAJOR COMMITTEE ASSIGNMENTS

- 1990-1992 Medical Executive Committee, Heritage Hospital
- 1991-1999 Medical Executive Committee, The Cambridge Hospital
- 1991-1998 Patient Care Improvement Committee, The Cambridge Hospital
- 1991-1996 Ambulatory Quality Assurance Committee, The Cambridge Hospital
- 1992-1999 Credentials Committee, The Cambridge Hospital
- 1992-1998 Institution Coordination Committee, The Cambridge Hospital
- 1992-1998 Surgical Case Review Committee, The Cambridge Hospital
- 1992-1998 Board of Trustees, The Cambridge Hospital Podiatry Residency Program
- 1992-1996 Operating Room Committee, The Cambridge Hospital

MAJOR ADMINISTRATIVE RESPONSIBILITIES:

- 1989-1998 Associate Director, The Cambridge Hospital Podiatry Residency Program
- 1991-1992 Director, Podiatry Residency Training Program, The Cambridge Hospital
- 1991-1998 Chief, Division of Podiatry, The Cambridge Hospital
- 1987-present Clinical Instructor, Division of Podiatry, The Cambridge Hospital

PROFESSIONAL SOCIETY INVOLVEMENTS:

- 1987 Member, American Podiatric Medical Association
- 1987 Member, Massachusetts Podiatric Medical Society

Edward J. Mostone, D.P.M.

Curriculum Vitae

Page 3 of 7

May 3, 2001

- 1987 Member, American Diabetes Association
- 1987 Member, American Association of Hospital Podiatrists
- 1987 Member, American Society of Regional Anesthesia
- 1987 Member, American Podiatric Circulatory Society
- 1991 Member, American College of Foot Surgeons
- 1992 Member, American College of Foot and Ankle Surgeons
- 1998 Member, American Public Health Association
- 1998 Member, American Academy of Pain Management
- 1998 Member, American Academy of Foot Orthopaedists

EDITORIAL BOARDS:

Self Report of Research, Teaching, Clinical Scholarship.

- 1985 Lecture Series, The Common Podiatric Problems for the General Practitioner, Medical Mission, San Paolo, Brazil
- 1985 Lecture Series, The Diabetic Foot and its Care, Medical Mission, San Paolo, Brazil
- 1985 Lecture, Prevention and Care of Foot Ulcers, Red Cross Nursing Staff, Medical Mission, San Paolo, Brazil
- 1985 Lecture, Assessment and risk factors for amputation in patients with diabetes mellitus, Medical Mission, San Paolo, Brazil
- 1988 The New Podiatric Physician, St. Vincent's Hospital Department of Medicine
- 1988 Lecture Series, Reverdin-Laird Bunionectomy, The Cambridge Hospital, Division of Podiatric Medicine
- 1989 Lecture Series, The Diabetic Foot, St. Vincent's Hospital Department of Podiatry.
- 1990 Lecture Series, The Surgical Approach to Hammertoe Deformity, The Cambridge Hospital, Division of Podiatric Medicine
- 1991 Lecture Series, Management of Fractures of the Forefoot, The Cambridge Hospital, Division of Podiatric Medicine
- 1991 Lecture Series, Reverdin-Laird Bunionectomy, St. Vincent's Hospital Department of Podiatry
- 1991 Lecture Series, Common Foot Problems in the Elderly, St. Vincent's Hospital Department of Podiatry
- 1987-1998 Facilitator, Resident's Journal Club, Department of Podiatric Medicine, The Cambridge Hospital
- 1992 Lecture Series, Treatment of Infections of the Lower Extremity, The Cambridge Hospital, Department of Medicine, Residency Teaching Program
- 1992 Lecture Series, Care of Bunions, Corns, Calluses and Ulcerations of the Feet, Primary Care Physicians, Fallon Clinic.
- 1992 Certifying Course Instructor, Lecturer, and Cadaver Laboratory Instructor, Ankle Arthroscopy and Endoscopic Plantar Fasciotomy, Boston University School of Medicine and The Cambridge Hospital, Division of Podiatry.
- 1993 Lecture Series, Common Podiatric Problems Treated at The Cambridge Hospital Emergency Department, The Cambridge Hospital

Edward J. Mostone, D.P.M.

Curriculum Vitae

Page 4 of 7

May 3, 2001

- 1994 Lecturer and Instructor, The History of Podiatry and Current Mandates of Residency Training Programs, Department of Internal Medicine, Fallon Medical Center
- 1994 Lecturer and Instructor, Certifying Program for Laser Surgery, The Cambridge Hospital, Division of Podiatric Medicine
- 1994 Lecturer, Podiatry Surgical Review Course, The Cambridge Hospital, Division of Podiatric Medicine
- 1994 Lecture Series, The Treatment of the Diabetic Foot, The Cambridge Hospital, Department of Medicine.
- 1995 Instructor, Common Foot Problems in the Elderly, Community Family Nursing Service, Everett/Medford, MA
- 1995 Instructor, Classification and treatment care plan for foot ulcers, Community Family Nursing Service, Everett/Medford, MA
- 1996 Grand Rounds, Surgical Approach to Hammertoe Deformity, Baltic American Clinic, Vilnius, Lithuania.
- 1996 Grand Rounds, Management of Open/Closed Fractures of the Foot, Vilnius University Emergency Hospital, Vilnius, Lithuania
- 1996 Grand Rounds, Fundamentals of Foot Surgery, Baltic American Clinic, Vilnius, Lithuania
- 1996 Grand Rounds, The Diabetic Foot; diagnosis, care and follow-up. Baltic American Clinic, Vilnius, Lithuania
- 1996 Lecture Series, Common Podiatric Problems Treated in the Emergency Room, Vilnius University Emergency Hospital, Vilnius, Lithuania
- 1996 Lecture Series, Puncture wounds: normal laboratory values vs. severe infection and antibiotic treatment. Vilnius University Emergency Hospital, Vilnius, Lithuania
- 1996 Grand Rounds, Peripheral vascular disease in the diabetic foot. Baltic American Clinic, Vilnius, Lithuania.
- 1996 Lecture Series, Classification and treatment care plan for foot ulcers, Division of Podiatry, Staten Island University Hospital
- 1996 Lecture Series, Medical and Surgical Management of Charcot's Arthropathy in patients with diabetes. Vilnius University Emergency Hospital, Vilnius, Lithuania.
- 1998 Soft Tissue Infection in the Diabetic Foot, Division of Podiatry, Staten Island University Hospital
- 1999 Lecture Series, Circulatory Problems in the Lower Extremity of the Diabetic, Division of Podiatry, Staten Island University Hospital.
- 1999 Lecture Series, Circulatory Problems in the Lower Extremity of the Diabetic, Physician Assistants, New England Medical Center.
- 1999 Footwear for the Diabetic, Cambridge Elder Services, City of Cambridge
- 1999 to present Resident's Journal Club, Division of Podiatric Medicine, The Cambridge Hospital

PUBLICATIONS AND TEXTS:

1. Walter M, Mostone E, Esposito F, Buxbaum F. The Keller-Austin Bunionectomy. J Foot Surg 26:5;pp400-405, 1987
2. Erwin R, Mintzer M, Greenberg L, Goldstein H, Berg A, Cohen H, Mostone E. Defense of Drunk Driving Cases, Criminal-Civil. Time Mirror Books, vol. 1, chapter 36, 1993

Edward J. Mostone, D.P.M.

Curriculum Vitae

Page 5 of 7

May 3, 2001

3. Carpenter B, Mostone E. The Cambridge Hospital Podiatry Manual, The Cambridge Hospital Library 1996
4. Mostone E. et al. Bunion Surgery, video. Division of Podiatry, The Cambridge Hospital Library, 1996
5. Miller J, Nath R, Stoughton A, Carpenter B, Mostone E. Streptococcal Toxic Shock Syndrome from a Puncture Wound to the Foot. J Foot Ankl Sur, vol 35, no.6, p578, Nov/Dec 1996.
6. Mostone E. et al. Hammertoe, video, Division of Podiatry, The Cambridge Hospital Library, 1997.
7. Killian F, Carpenter B, Mostone E. Dorsal Dislocation of the First Metatarsophalangeal Joint. J Foot Surg, vol 35, no. 2, p131, Mar/Apr 1997.
8. Author; "Achilles Tendonitis" Fallon Quarterly Community Health Guide, Fall 2000

Edward J. Mostone, D.P.M.

Curriculum Vitae

Page 6 of 7

May 3, 2001

REFERENCES AND BIBLIOGRAPHY:

1. Reiber GE, Pecoraro RE, Koepsell TD. Risk factors for amputation in patients with diabetes mellitus. A case-control study. *Ann Intern Med* 1992; 117:97-105.
2. Armstrong DG, Lavery LA, Quebedeaux TL, Walker SC. Surgical morbidity and the risk of amputation due to infected puncture wounds in diabetic versus nondiabetic adults. *South Med J* 1997;90:384-9.
3. Gibbons G, Eliopoulos GM. Infection of the diabetic foot. In: Kozak GP, et al., eds. *Management of diabetic foot problems*. Philadelphia: Saunders. 1984:97-102.
4. Pecoraro RE, Reiber GE, Burgess EM. Pathways to diabetic limb amputation. Basis for prevention. *Diabetes Care* 1990;13:513-21.
5. Lavery LA, Ashry HR, van Houtum W, Pugh JA, Harkless LB, Basu S. Variation in the incidence and proportion of diabetes-related amputations in minorities. *Diabetes Care* 1996;19:48-52.
6. Edmonds ME. Experience in a multidisciplinary diabetic foot clinic. In: Connor II, Boulton AJ, Ward JD, eds. *The foot in diabetes: proceedings of the 1st National Conference on the diabetic Foot*, Malvern, May 1986. Chichester, N.Y.: Wiley, 1987:121-31.
7. Wylie-Rosset J, Walker EA, Shamooh H, Engel S, Basch C, Zybert P. Assessment of documented foot examinations for patients with diabetes in inner-city primary care clinics. *Arch Fam Med* 1995;4:46-50.
8. United States National Diabetes Advisory Board. The national long-range plan to combat diabetes. Bethesda, Md.: U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, 1987; NIH publication number 88-1587.
9. Bailey TS, Yu HM, Rayfield EJ. Patterns of foot examination in a diabetes clinic. *Am J Med* 1985; 78:371-4.
10. Edelson GW, Armstrong DG, Lavery LA, Caicco G. The acutely infected diabetic foot is not adequately evaluated in an inpatient setting. *Arch Intern Med* 1996;156:2373-8.
11. Kannel WB, McGee DL. Diabetes and glucose tolerance as risk factors for cardiovascular disease: the Framingham study. *Diabetes Care* 1979;2:120-6.
12. LoGerfo FW, Coffman JD. Vascular and microvascular disease of the foot in diabetes. Implications for foot care. *N Engl J Med* 1984;311:1615-9.
13. Lee JS, Lu M, Lee VS, Russell D, Bahr C, Lee FT. Lower-extremity amputation. Incidence, risk factors, and mortality in the Oklahoma Indian Diabetes Study. *Diabetes* 1993;42:876-82.
14. Kannel WB, McGee DL. Update on some epidemiologic features of intermittent claudication: the Framingham study. *J Am Geriatr Soc* 1985;33: 13-8.
15. Bacharach JM, Rooke TW, Osmundson PJ, Gliovizki P. Predictive value of transcutaneous oxygen pressure and amputation success by use of supine and elevation measurements. *J Vasc Surg* 1992;15:558-63.
16. Apelqvist J, Castenfors, Larsson J, Stenstrom A, Agardh CD. Prognostic value of systolic ankle and toe blood pressure levels in outcome of diabetic foot ulcer. *Diabetes Care* 1989;12:373-8.
17. Caputo GM, Cavanagh PR, Ulbrecht JS, Gibbons GW, Karchmer AW. Assessment and management of foot disease in patients with diabetes. *N Engl J Med* 1994;331 :854-60.

Edward J. Mostone, D.P.M.

Curriculum Vitae

Page 7 of 7

May 3, 2001

18. Harati Y. Diabetic peripheral neuropathy. In: Kominsky SJ, ed. Medical and surgical management of the diabetic foot. St. Louis: Mosby, 1994:73-85.
19. Orchard TJ, Strandness DE Jr. Assessment of peripheral vascular disease in diabetes. Report and recommendation of an international workshop sponsored by the American Heart Association and the American Diabetes Association 1820 September 1992, New Orleans, Louisiana. J Am Podiatr Med Assoc 1993;83:685-95.
20. Brand PW. The insensitive foot (including leprosy). In: Jahss MII, ed. Disorders of the foot & ankle: medical and surgical management. 2d ed. Philadelphia: Saunders, 1991:2173-5.
21. Armstrong DG, Todd WF, Lavery LA, Harkless LB, Bushanan TR. The natural history of acute Charcot's arthropathy in a diabetic foot specialty clinic. Diabet Med 1997;14:357-63.
22. Edmonds ME, Clarke MB, Newton S, Barren J, Watkins Pt. Increased uptake of bone radiopharmaceutical in diabetic neuropathy. Q J Med 1985;57: 843-55.
23. Brower AC, Allman PM. The neuropathetic joint: a neurovascular bone disorder. Radiol Clin North Am 1981;19:571-80.
24. Birke JA, Sims DS. Plantar sensory threshold in the ulcerative foot. Lcpr Rev 1986;57:261-7.
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26. Bild DE et al. Lower-extremity amputation in people with diabetes. Epidemiology and prevention. Diabetes Care 1989;12:24-31.
27. Lavery LA et al. Puncture wounds: normal laboratory values in the face of severe infection in diabetics and non-diabetics. Am J Med 1996;101:521-5.
28. Grayson ML, Gibbons OW, Balogh K, Levin B, Karchmer AW, Probing to bone in infected pedal ulcers. A clinical sign of underlying osteomyelitis in diabetic patients. JAMA 1995;273:721-3.
29. Sutter CW, Shelton DK. Three-phase bone scan in osteomyelitis and other musculoskeletal disorders. Am Fam Physician 1996;54:1639-47.
30. Lavery LA et al. Classification of diabetic foot wounds. J Foot Ankle Surg 1996;35:528-31.
31. Armstrong DG et al. Treatment-based classification system for assessment and care of diabetic feet. J Am Podiatr Med Assoc 1996;86:311-6.
32. Sarrafian, SK. Anatomy of the foot and ankle: descriptive, typographic, functional., out of print. Lippincott Williams & Wilkins 1993.
33. Yale, I. Arthritic foot and related connective tissue disorders., out of print. Lippincott Williams and Wilkins 1984.
34. Shereff, MJ. Atlas of foot and ankle surgery. WB Saunders 1993.
35. Dockery, GL. et al. Color atlas of foot and ankle dermatology. 1st edition, Lippincott Williams & Wilkins 1999.
36. Birrer, RB. common foot problems in primary care. 2nd edition, Hanley & Belfus 1992.
37. Boulton, AJ et al. The foot in diabetes. 1st edition, Wiley, John & Sons Inc 2000.
38. Subtonick, SL. Sports medicine of the lower extremity. 2nd edition, WB Saunders 1999.